

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

THIS PAGE BLANK (USPTO)



RESERVE COPY

PATENT SPECIFICATION

Convention Date (United States): May 5, 1936.

489,316

Application Date (in United Kingdom): April 27, 1937. No. 12033/37.

Complete Specification Accepted: July 25, 1938.

COMPLETE SPECIFICATION

Improvements in or relating to Devices for use in Surgery

We, DAVIS & GECK, INC., a corporation organised under the Laws of the State of New York, United States of America, of 217, Duffield Street, Brooklyn, New York, United States of America, do hereby declare the nature of this invention and in what manner the same is to be performed, to be particularly described and ascertained in and by the following statement:—

This invention relates to devices for use in surgery, and to methods of producing such devices.

As long ago as 1774, Leconte advocated wrapping a section of a goose quill around a wounded blood vessel holding it in place with a ligature. Later Latteri and Petrinari reported the use of implanted magnesium tubes and quills of doves' feathers for end to end anastomosis of the severed common bile duct using such tubes and quills. Today the use of Murphy buttons for end to end anastomosis of the severed or strictured intestinal tract is well known. Difficulties are encountered in these situations in that after the parts have healed, the non-absorbable tubes, or buttons must be removed, accomplished usually by dislodgment and subsequent passage out of the system by the patient.

The principal object of the invention is to avoid the necessity of removal of such tubes, and with this end in view, the invention provides a sterile tube constructed artificially from absorbable animal tissue which is readily absorbed or digested by the body during or subsequent to the repair period. The term "constructed artificially" used here and in the appended claims means, for the present purpose that the tube is made up from material in strip, cord or pulp form which is wound, wrapped, braided, moulded or otherwise formed into a tube, and does not mean that the tube is a naturally occurring tube artificially treated to modify its character while retaining its tubular form. The tube of this invention may be made straight, angular, curved, Y-shaped or T-shaped, and may be of such absorbable animal

tissue as the submucosa layer of animal intestinal tissue.

The invention further contemplates a method of making the improved tube of absorbable animal tissue. This may be done by wrapping, winding, spinning or forming the tissue over a mandrel or core, form pressing the tissue to shape and subsequently removing the core. For this purpose, the animal tissue may be in the form of threads, ribbons or a pulp to which a binder such as glue has been added so that upon formation of the material into a tube, the material will harden in that shape and maintain its form.

It has been proposed to make flexible tubes intended to convey petrol, oil and the like by winding successive layers of intestinal membrane or skin spirally upon a former, the tubing being reinforced if desired by the introduction between the layers of an extensibly woven or otherwise suitably prepared or cut fabric.

It has also been proposed to use gelatine in the production of tubes for medical purposes e.g. for catheters, drainage tubes etc. by applying successive coatings of a gelatine mix to a mandrel, by moulding the product in a pasty condition or by winding on to a mandrel a continuous bond.

Perhaps the uses to which the tubes of this character may be put may be readily separated into five types of situations, as follows:

1. End to end, end to side, or side to side anastomosis;
2. Transplantation of one duct into another;
3. Structural support for reconstruction or repair;
4. Used as an exterior sheath to protect a transplanted nerve, tendon or the like;
5. Used for drainage purposes, with or without wicks.

The invention further consists in the novel construction, arrangement and combination of parts and methods of manufacture more fully hereinafter described with reference to the drawings:

In the drawings:

Figure 1 shows a complete tube of this invention;

Figure 2 shows a modified form of tube with depressions in its end portions;

Figure 3 shows a collared bobbin;

Figure 4 is a modified bobbin or tube with collars at each end;

Figure 5 shows a spool-shaped tube or bobbin;

Figure 6 illustrates a di-conical shaped tube;

Figure 7 shows a completed Y-tube;

Figure 7a illustrates a completed T-tube;

Figure 8 shows the method of wrapping tapes on a mandrel in the manufacture of a tube prior to form pressing where that is desirable;

Figure 9 shows a tube in the process of being formed from cords;

Figure 10 shows a tube in the process of being manufactured from woven strands;

Figure 11 is a composite view of a two-part mandrel for the manufacture of T-tubes;

Figure 12 shows the manner of winding a tape on the T-shaped mandrel of Figure 11;

Figure 12a shows the completely wound strip on the T-mandrel;

Referring now with particularity to the drawings, in Fig. 1 there is shown perhaps the most common type of tube or bobbin, to wit: a straight, hollow element of elongated nature, the dimensions of such an article being variable, of course, dependent upon the situation in which it is to be used. The words "tube" and "bobbin" are herein used interchangeably as their difference relates only to dimensions. A short, stubby tube may be termed a bobbin.

In Fig. 2, a modified form of tube is shown at 2 having a slightly depressed groove 3 at the end portion thereof. This form is particularly desirable in an end to end anastomosis in that it facilitates ligaturing the incised ends of the duct. The grooves 3 may be formed by pressing or moulding the material upon the form on which it is produced.

In Fig. 3, a tube is shown at 4 having a collar 5 at one end which may be desirable in some instances.

In Fig. 4, the tube 4 is provided with collars 5 and 6 at each end.

In Fig. 5, a spool shaped tube 7 is shown which involves all of the desirable attributes of the tube of Fig. 2 in that ligaturing is facilitated. This embodiment resembles the embodiment illustrated in Figure 4 but differs therefrom in that the ends are smoothly flared outwardly instead of meeting the body of the

spool in abrupt edges as in the arrangement illustrated in the previous figure.

The spool shape of the tube may be further accentuated into the form shown in Fig. 6 where at 8 the tube is di-conical in shape, that is, it consists essentially of two frusto-conical configurations with their smaller bases contiguous.

In Figs. 7 and 7a, Y and T-shaped tubes are shown respectively.

In manufacturing these shapes, any suitable absorbable animal tissue may be utilized which will have or can be made to have desirable rigidity, absorbability and freedom from a tendency to produce tissue irritation. The tissue must likewise be capable of withstanding heat or chemical sterilization. The best material of which I am aware from which these tubes may be made is the submucous layer of animal intestinal tissue.

This material in either the form of threads or ribbons may then be wound over a metal or other form to give it the desired shape. For instance, in Fig. 8 a ribbon 9 may be spirally wound over a metal form 10, slightly overlapping the convolutions, and the core 10 subsequently removed after the ribbon has been permitted to assume a self-sustaining condition.

In Fig. 9, threads 11 are spirally wound, woven or spun over the core 10 in the same manner as recited for that of Fig. 8. It has been found that in this type of manufacture, the contact of the threads with each other is sufficient to cause a coalescence therebetween with the result that an eventually integral construction results.

In Fig. 10, a modified form of weaving is shown over the core 10, where these strands may be either in the form of threads or ribbons.

Where Y or T-tubes are to be made, it will be desirable to provide a two-part core such, for instance, as is shown in Fig. 11. There one arm is shown at 12 having a threaded socket 13 in which the leg 14 may be screwed. Obviously, where a Y-tube is desired instead of a T, one arm of the Y may be screw-connected to a member constituting the other arm and the leg of the Y. In manufacturing a T tube from the two-part core of Fig. 11, reference is had to Fig. 12 and 12a using preferably a ribbon material, such for instance, as is shown in Fig. 8. In this instance, the ribbon may be wound on the core beginning at one end of the arm, spirally around that arm from the end toward the center. At the center, it is criss-crossed down the leg 14 to the end, back again upon itself and out to the opposite end of the arm 12. Where

desired, a second or any number of additional layers may be superimposed in the same manner and beginning at the opposite end of the arm 12. When the winding has been completed and the material is self-sustaining, the core may be disconnected by unscrewing the leg 14 from the arm 12 followed by subsequent removal of the latter. In the case of a Y-tube, the member constituting the one arm and leg of the Y must be removed before the tube is completely rigid.

Obviously, absorbable straight, Y or T-tubes of animal tissue may be made also by winding or spinning gut threads or narrow gut ribbons or strips spirally or transversely over a form and held together by a binder of glue or similar substance.

In all cases, it is desirable to form press the material of the tubes or bobbins to shape, either with or without heat, as this materially assists in bringing the tube to a self-sustaining condition with smooth surfaces. This action, therefore, eliminates to a great extent the irregularities in the surface of the articles shown, for instance, in Figs. 8, 9, 10, 12 and 12a.

For the purpose of retarding absorption by animal tissue, the absorbable tubes may be further treated. The methods which I have devised for the purpose may consist of: 1) immersion of the absorbable tube in a solution of formaldehyde; 2) immersion of the tube in a liquid petroleum product such as that on the market under the Registered Trade Mark "Albolene"; 3) coating the tube with keratin; 4) coating the tube with paraffine; and 5) coating the tube with resinous material.

Having now particularly described and ascertained the nature of our said invention and in what manner the same is to be performed, we declare that what we claim is:—

1. A device for use in surgery as an aid to anastomosis, or for drainage purposes and the like, comprising a sterile tube constructed artificially from absorbable animal tissue.

2. A device for use in surgery, as for example, as an aid to anastomosis, or for drainage purposes and the like, comprising a sterile Y-tube constructed artificially from absorbable animal tissue, and adapted to be inserted into and left in the body to be absorbed thereby.

3. A device for use in surgery, as for example, as an aid to anastomosis, or for drainage purposes and the like, comprising a sterile T-tube constructed artificially from absorbable animal tissue, and adapted to be inserted into and left in the body to be absorbed thereby.

4. A method of making a tubular article for use in surgery which comprises applying absorbable animal tissue to a mandrel to form a tube, the mandrel being removed when the tube becomes self-sustaining, and sterilizing the tube.

5. A method as claimed in claim 4, in which the animal tissue is form pressed on the mandrel before the latter is removed.

6. A method of making a tubular article for use in surgery, which comprises winding animal tissue helically in one direction around a mandrel and then back in a reverse direction, to form a tube, the mandrel being removed when the tube becomes self-sustaining, and sterilizing the tube.

7. The improved device for use in surgery, substantially as hereinbefore described, with reference to the several embodiments illustrated in the accompanying drawings.

8. A method of making a tubular article for use in surgery, substantially as hereinbefore described, with reference to the accompanying drawings, for the purpose specified.

Dated this 27th day of April, 1937.

For: DAVIS & GECK, INC.,
Stevens, Langner, Parry & Rollinson,
Chartered Patent Agents,
5—9, Quality Court, Chancery Lane,
London, W.C.2, and at
120, East 41st Street, New York,
U.S.A.

Fig. 1.

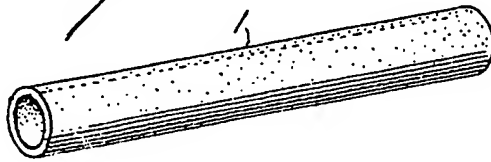


Fig. 2.

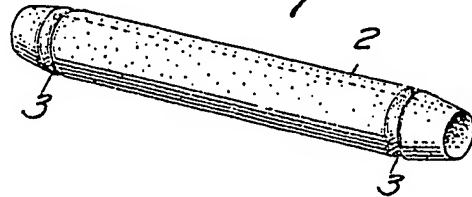


Fig. 3.

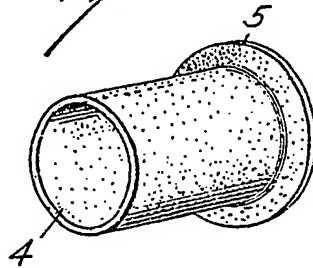


Fig. 4.

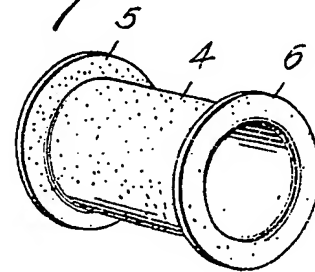


Fig. 5.

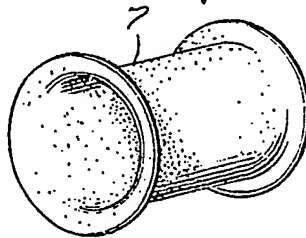


Fig. 6.

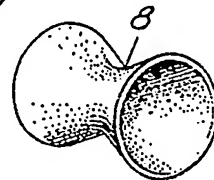


Fig. 7.

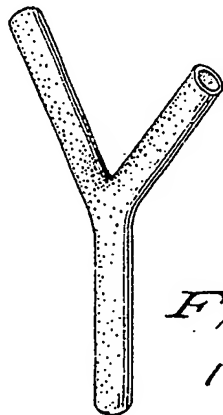
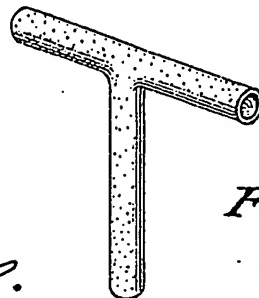


Fig. 7a.



[This Drawing is a reproduction of the Original on a reduced scale.]

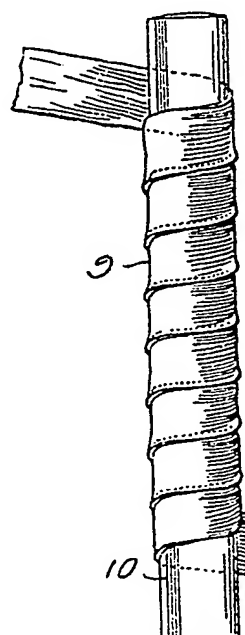


Fig. 9.

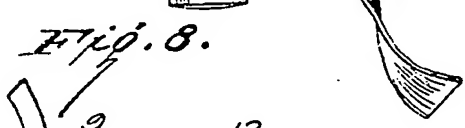
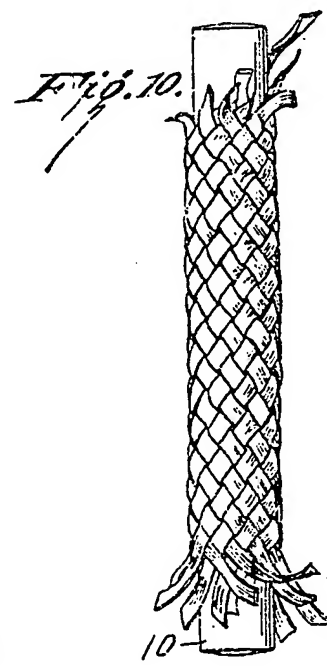


Fig. 8.

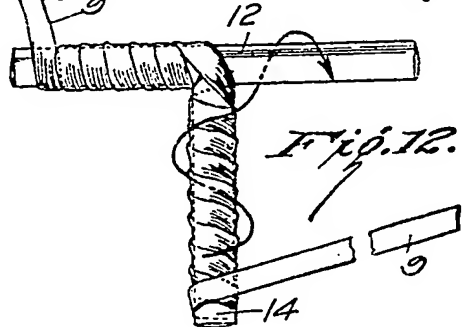


Fig. 12.

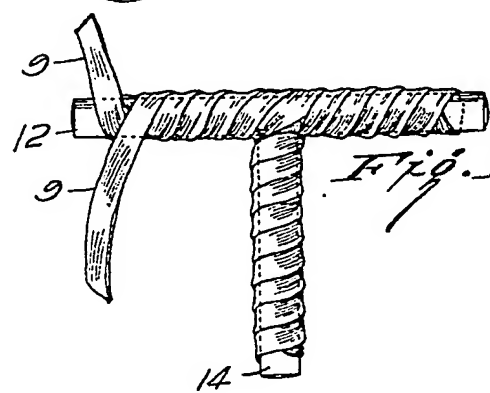


Fig. 12a.

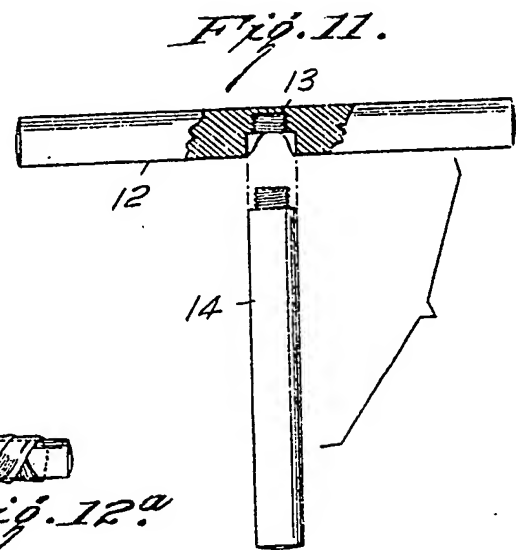
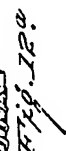
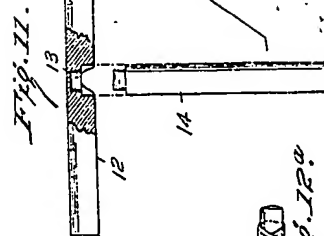
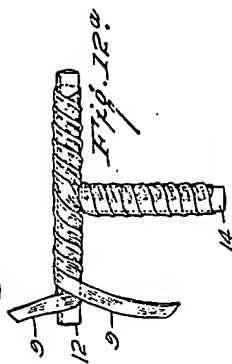
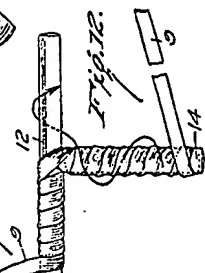
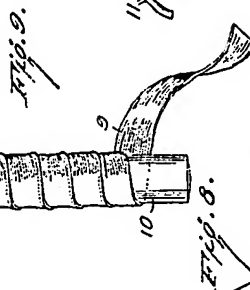
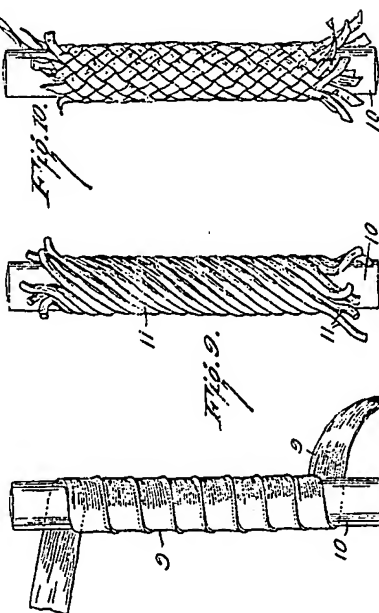
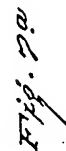
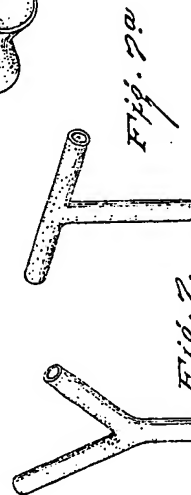
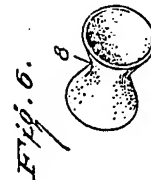
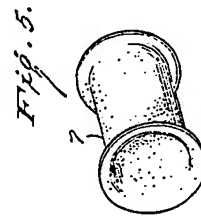
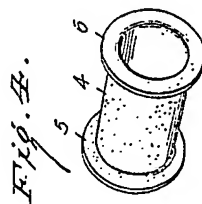
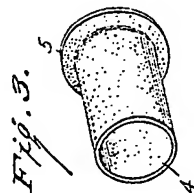
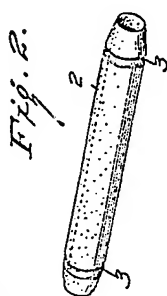
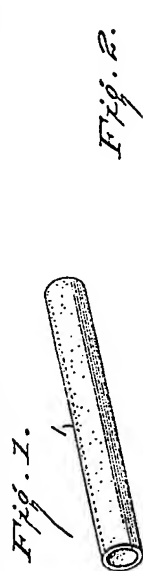


Fig. 11.



[This Drawing is a reproduction of the Original on a reduced scale]